UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,300	08/22/2003	Hani Fares	LOREAL 3.0-039/OA03326	9219

530 7590 04/16/2008

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
04/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/646,300	FARES ET AL.	
	Examiner	Art Unit	
	LEONARD M. WILLIAMS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-40* is/are pending in the application.

4a) Of the above claim(s) *39 and 40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/28/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 01/28/2008 has been entered.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Amendment/Arguments

In the claims filed with the RCE on 01/28/2008 no amendments were made to the claims.

Applicant's arguments filed 01/28/2008 have been fully considered but they are not persuasive. The applicant's argue on page 6 of the remarks that there is no search burden on the examiner for the new method claims 39 and 40 presented previously and withdrawn by the examiner under original presentation. The applicant's assert that the two new claims are simply methods of formulation of hydrocortisone. The examiner respectfully disagrees. If the claims were to be considered as non-independent and simply as methods of formulating then why did the applicant write the claims as independent and not begin the claims with the same language as the methods of formulating previously considered? Further the applicant's argue that the examiner did not fully demonstrate burden or even show a different classification of the withdrawn claims. The examiner has examined claims 1-38, which include a composition, a method of formulating, and a method for treating all using the composition. Thus applicants have been given one set of composition claims, one set of method of making claims and one set of method of using claims. Claims 39 and 40

clearly are drawn to methods of using the composition different from the already examined methods of making and treating (and/or using). The applicant's have sought to add additional inventions after several office actions have been completed and sent out on the previous claims 1-38. The examiner set forth the reasons why the claims were withdrawn under original presentation in the last office action and refer applicants back to said office action.

The applicant's have included the same arguments that have been presented previously with no additional amendments to the claims. The applicant's are arguing unexpected results that exist within the specification, as well as the Fares declaration, and state that the examiner has failed to put forth any reasoning in regards to the unexpected results. The examiner respectfully disagrees. The specification has been considered and the Fares declaration has been considered as indicated both in the lengthy interview of 11/10/2005 and the last office action on page 3. The examiner has clearly indicated that the declaration sets forth only the reasoning why applicant's chose pentylene glycol. The examiner has set forth a clear prima facie obviousness case with a different motivation and reasoning why pentylene glycol would be utilized.

All rejections of the last office action are maintained and this action is made **final**.

The rejections of the last office action are reproduced below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US Patent No. 6113888), in view of Cooper et al. (US Patent No. 4552872), in view of Quigley et al. (US Patent No. 6075056), and further in view of VollHardt et al. (US Patent No. 6274124).

Castro et al. teach, in col. 2 lines 35-55 and claim 21, a mousse composition for topical application that includes 0.001% to about 20% of 1,2-pentanediol and 0.001% to about 20% of 2-methyl-1,3-propanediol, in col. 4 line 60 to col. 5 line 15, Castro et al. teach dermatologically active agents that can be added to the said mousse compositions as including hydrocortisone, dexamethasone, panthenol, phenol, betamethasone, and triamcinolone.

Castro et al. teach, in col. 5 lines 48-55, examples of humectants that can be used in the compositions including glycols such as 2-methyl-1,3-propanediol, 1,2-pentanediol, hexylene glycol, and propylene glycol.

Castro et al. does not teach hydrocortisone acetate and triamcinolone acetate and their respective percentages in the compositions, nor does Castro et al. teach butylene glycol as a solvent or that butylene glycol and propylene glycol can be used together.

Cooper et al. teach, in col. 8 lines 55-63, diol compounds for use in topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols.

Cooper et al. teach, in col. 8 lines 10-50, corticosteroids for use in the topical pharmaceutical compositions including hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. The compositions are to contain a safe and effective amount of corticosteroid from about 0.01% to about 10%, more preferably from about 0.02% to about 5%, and most preferably from about 0.05% to about 5% of corticosteroid. In examples 1-31 Cooper et al. disclose a variety of topical pharmaceutical compositions containing various corticosteroids and diols and that the compositions show enhanced penetration of the corticosteroids when applied topically.

Quigley et al., in col. 7 lines 30-65 and Table A, teach topical formulations that may be in the form of creams, ointments, gels, lotions, foams, powders, shampoos

and/or liquid solutions comprising a steroid (0.01-2.5% by weight) and propylene glycol (5-20% by weight), wherein the steroid can be triamcinolone acetate.

Vollhardt teaches, in col. 3 lines 25-45, cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt details that 1,2-pentanediol should preferably represent 0.5% to 6% by weight of the composition, and that 1,2-pentanediol gives improved water resistance to the compositions as compared to 1,2-propanediol and 1,2-hexanediol.

Vollhardt teaches, in col. 3 lines 50-65, that the cosmetic and/or dermatological formulations can be in the form of an emulsion, thin lotion, creamy lotion, light cream, gel, and mousse formulations.

Vollhardt teaches, in col. 4 line 50 to col. 5 line 5, that the cosmetic and/or dermatologically active agents include steroidal anti-inflammatory agents such as hydrocortisone, non-steroidal anti-inflammatory agents, anti-microbial agents and fragrances.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine Castro et al. with Cooper et al. in view of Vollhardt.

One of ordinary skill in the art at the time the invention was made would have been motivated to combine Castro et al. with Cooper et al. in view of Quigley et al. and Vollhardt because Castro et al. discloses topical compositions comprising 1,2-pentanediol, an additional glycol (2-methyl-1,3-propanediol), and a dermatologically

active agent (which could be hydrocortisone or triamcinolone). Cooper et al. discloses topical pharmaceutical corticosteroid compositions including 1,2-propanediol, 1,3-propanediol, 1,2-butanediol, 1,3-butanediol, 1,4-butanediol or mixtures of these diols. Cooper et al. discloses that the topical pharmaceutical corticosteroids used in the compositions include hydrocortisone, hydrocortisone butyrate, hydrocortisone acetate, triamcinolone, and triamcinolone acetonide. Quigley et al. teach topical formulations of triamcinolone acetate and propylene glycol. Vollhardt teaches cosmetic and/or dermatological formulations comprising 1,2-pentanediol and at least one cosmetic or dermatological active agent in a cosmetically and/or pharmaceutically acceptable carrier for topical application to the skin. Vollhardt teaches that the cosmetic or dermatologically active agent can be a steroidal anti-inflammatory such as hydrocortisone. Vollhardt also discloses that 1,2-pentanediol confers greater water resistance to compositions. It would have been obvious to one of ordinary skill in the art at the time the invention was made that 1,2-pentanediol could be used in the topical pharmaceutical corticosteroid compositions of Cooper et al., in view of Vollhardt, as Castro et al. demonstrated that 1,2-pentanediol could be combined with another diol (propylene glycol or butylenes glycol or both) and that Castro et al., Cooper et al. and Vollhardt's compositions all contain the same dermatologically active agents (steroidal anti-inflammatories). Quigley et al. demonstrate that triamcinolone acetate is an acceptable steroidal anti-inflammatory for glycol formulations. The increased water resistance properties of 1,2-pentanediol containing compositions would motivate one of ordinary skill in the art to combine the compositions. A reasonable chance of success

would be expected as the compositions demonstrate that 1,2-pentanediol can be combined with additional diols and all the compositions detailed include steroidal anti-inflammatory agents exemplified by hydrocortisone.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEONARD M. WILLIAMS whose telephone number is (571)272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. M. W./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617

Application Number	Application/Control No.	Applicant(s)/Patent under Reexamination	
	10/646,300	FARES ET AL.	
	Examiner	Art Unit	
	LEONARD M. WILLIAMS	1617	